CHAPTER ONE

INTRODUCTION

1.1 Introduction:

Nuclear medicine and therapeutic procedures use different radioactive isotopes for radiation diagnostic and therapeutic purposes. The amount of radioactivity has to be determined exactly before administration to patients. The isotope calibrators have to measure the radioactivity of gamma and beta emitting isotopes with different energies precisely for high quality images and for applying the right amount of radiation dose for treatment of disease. They must be able to measure low isotope activities for patient application and high activities during isotope production. The isotope calibrators should allow easy and fast operation in routine work as well as quick and effective cleaning in case of contamination. Continuous quality control of isotope calibrators is mandatory according to international standards and guidelines such as international electro-technical committee, IEC 61303 "Medical electrical equipment –Radionuclide calibrators– Particular methods for describing performance". Those methods include background measurement, accuracy, reproducibility and linearity checks as well as contamination tests. All these parameters influence the quality of activity measurements and consequently the radiation load for the patients. The high quality isotope calibrators assist responsible staffs in nuclear medicine laboratories to perform precise activity measurements and to fulfill the ICRP 60requirement to keep the radiation load as low as achievable for patients The radionuclide activity dose calibrators are routinely used in nuclear medicine practices to quantify the radioactivity dose of the radiopharmaceuticals to be administered to the patients. According to the current standards and regulations for NM worldwide practices, including those adopted by the international atomic energy agency (IAEA), and national regulations such as those promulgated by the United States Nuclear Regulatory Commission (U.S.NRC), the radioactivity of any radiopharmaceutical that contains a photon-emitting radionuclide must be measured by a dose calibrator prior to administration to patients or for

human research purposes. Obviously, the administration of the prescribed amount of activity to the patient requires proper operation of the dose calibrator, which shall be verified by implementing the required quality control tests on the instrument. Several quality control tests are necessary to ensure the proper operation of the dose calibrators, among which the tests for the linearity of the response, accuracy, precision, and physical functioning of the instrument are more important. The linearity of the response test confirms the ability of the instrument to measure a range of low to high activity doses with a required degree of accuracy. It is important that the linearity of the response of the dose calibrator to be ascertained over the range of its use between the maximum activity administered and 1MBq. It has been recommended that the test to be carried out up on acceptance, repair, and then annually. This test is mostly carried out by measuring a high activity, short-lived radionuclide for a given period of time by the instrument. Typically, ^{99m}Tc is used for this purpose. Accuracy is a quality control measure performed up on acceptance, repair, and then annually, to ensure that the activity values determined by the dose calibrator are traceable to national or international standards of radioactivity within the indicated uncertainties. Precision test is to confirm that the random uncertainty of a single measurement is primarily determined by the random nature of radioactive decay. A larger than expected value indicates the possible presence of another random source of uncertainty that had not been anticipated. The recommended values for the above QC measures are within ±5 to ±10 %, depending on the radionuclide of interest and measurement conditions. (Yousif M, 2015, International Journal of Science and Research).

1.2 Problem of the Study:

Quality control checks of dose calibrators is performed to assay patient dosage and are essential to ensure that the dosage administered to patient is the same as the prescribed dosage ,There are many problems that arise due to absence of quality control of dose calibrator which are used for dose measurements in some nuclear medicine departments , therefore many patients may take inaccurate dose.

1.3 Objectives of the Study:

1.3.1 General Objective:

The main objective of the study is to evaluate Dose Calibrator Performance in Royal Care International Hospital.

1.3.2 Specific Objectives:

- To measure the precision of dose calibrator.
- To test the calibrator linearity.
- To perform geometry test to the dose calibrator.

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1.4 Research Outlines:

This study falls into five chapters, Chapter one which is an introduction, it presents the statement of the study problems, objectives and the overview of the study. Chapter two contains the literature review also includes a summary of previous study performed in this field. Chapter three describes the materials and a method used. Chapter four deals with the results and finally chapter five shows the discussion, conclusion and recommendations and references list and appendices.

CHAPTER TWO

LITERATURE REVIEW

2.1 Theoretical Background:

2.1.1 Radionuclide dose calibrators (activity meters):

An ionization chamber is an instrument constructed to measure the number of ions within a medium. It usually consists of a gas filled enclosure between two conducting electrodes (the anode and cathode). When gas between the electrodes is ionized by any means, such as by gamma rays or other radioactive emission, the ions and dissociated electrons move to the electrodes of the opposite polarity, thus creating an ionization current which may be measured. Eachion essentially deposits or removes a small electric charge to or from an electrode, such that the accumulated charge is proportional to the number of like-charged ions. A voltage potential that can have a wide range from a few volts to many kilovolts can be applied between the electrodes; depending on the application. Ionization chambers are widely used in the nuclear industry as they provide an output that is proportional to radiation dose.
(International Atomic Energy Agency (IAEA), 2016)

2.1.2 Basic Principles:

A radionuclide calibrator is in essence a well-type gas ionization chamber into the well of which a radioactive material is introduced for measurement. The activity of the material is measured in terms of the ionization current produced by the emitted radiations which interact in the gas. The chamber is sealed, usually under pressure, and has two co-axial cylindrical electrodes maintained at a voltage difference derived from a suitable supply, the axial space constituting the well In the associated electrometer, the ionization current is converted to a voltage signal, which is amplified, processed and finally displayed, commonly in digital form in units of activity – Becquerel (Bq) or curies(Ci). This is possible since for a given radionuclide, assuming a fixed geometry and a linear response, ionization current is directly proportional to activity. However, the response of an ionization chamber to the radiations from different radio-nuclides varies according to the types, energies and abundances of these radiations, the primary consideration being the rate

of emission of photon energy. Appropriate adjustment of the amplification of the voltage signal is thus necessary, if the display with different radionuclides is always to be in units of activity. Most radionuclide calibrators have selector switches, selector push-buttons or plug-in modules for different radionuclides, which achieve this adjustment by selecting a fixed resistor determining the amplification. Alternatively or additionally, a continuously variable resistor (potentiometer) with a dial which can be set to a specified number according to radionuclide to be measured may be provided.
Lead shielding around the ionization chamber provides protection to Personnel against radiation hazards and reduces its response to environmental radiation, but a residual background response remains.
Some radionuclide calibrators have a continuously adjustable zero control by which this response may be "backed off". Otherwise, it must be noted and subtracted, if significant, from subsequently measured activities.
A removable liner that can be easily cleaned in the event of accidental radioactive contamination of the chamber well is usually provided. (IAEA-TECDOC-602, 1991)

The dose calibrator is one of the most essential instruments in nuclear medicine for measuring the activity of radionuclides for formulating and dispensing radiopharmaceuticals. It is a cylindrically shaped, sealed chamber made with two concentric walls and a central well. It is filled with argon and traces of halogen at high pressure. Its operating voltageisabout150V.
A typical dose calibrator is shown in Fig 2.1**:**

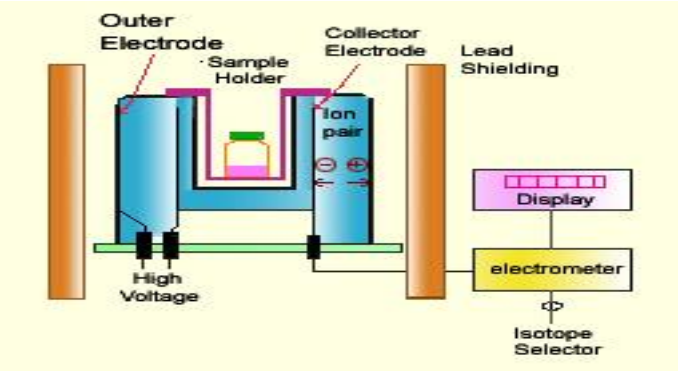

Figure 2.1 shows radionuclide calibrator

2.1.3 Operational Considerations:

The accuracy of a radionuclide calibrator depends upon several factors. Every such instrument is factory-calibrated with a set of certified sources that, at best, are within ±1% of their stated activities, but may be only within ± 3%, or even ±5%, limiting the initial accuracy. This initial accuracy may change with time as a result of changing pressure of the chamber gas and slow electronic drift. The addition of lead shielding may also significantly affect the accuracy of a radionuclide calibrator because of the extra contribution of scattered radiation from the added shielding, necessitating changes in calibration settings. Further, the accuracy of any individual measurement is dependent upon the similarity of the measured material to the original calibration source. Especially with radionuclides giving low-energy radiations, differing radiation absorption characteristics of the material may cause significant measurement errors. (IAEA-TECDO-602, 1991)

All radionuclide calibrators show some dependence on measurement geometry; this effect diminishes with increasing depth of the well. With many such instruments, tables are provided giving correction factors to be applied in measurements on different radionuclides in syringes, vials and other containers of different sizes and types. However, nuclear medicine units should determine correction factors appropriate to their own situations. It should be appreciated that correction factors for syringes depend on whether or not a needle is attached. (IAEA-TECDO-602, 1991)

Simple operational checks of reproducibility of performance and background response are needed each day a radionuclide calibrator is used. In addition, regular quality control should cover its precision, its accuracy and the linearity of its activity response.

Table 2.1 lists the recommended quality control tests for a radionuclide calibrator, with suggested frequencies for the repetition of reference tests in routine testing. The operational checks should be carried out each day the instrument is used. (IAEA-TECDO-602, 1991)

Table 2.1 Shows Test Schedule for Radionuclide Calibrator (IAEA-TECDO-602, 1991)

Test No	**Test**	**Acceptance**	**Reference**	**Frequency in routine testing**		
Acceptance and Reference Tests				Weekly	Quarterly	Half-yearly
2.3.1	Physical Inspection	√				
2.3.2	Test of Precision and Accuracy	√	√		√	
2.3.3	Test of Linearity of Activity Response	√	√		√	
2.3.4	Test of Background Response	√	√	√		
Operational Checks						
2.4.1	Check of Reproducibility					
2.4.2	Check of Background Response					

Figure 2.2 A radionuclide dose calibrator, Biodex model Atomlab 500. (Photo courtesy of Biodex Medical Systems, Inc.)

2.1.4 International Standards:

International standards play a very important role in QC management. Many basic QC Procedures are included in the international standards and it appears that the primary duty of those responsible for the quality of a product or service is to comply with requirements included in the standards.
Nuclear instruments are a rather specialized topic, as they must meet not only general requirements concerning QC, but also strict rules related to ionization radiation. The list presented below contains only those international standards, which refer to products and services related to ionization radiation.
From among several tens of thousands of international standards, about Five hundred connected with ionization radiation were found. (IAEA-TECDOC-1599, 2008)

2.1.5 Organization Developing International Standards:

There are several organizations developing international standards, ISO, IEC, CEN, CENELEC, and ETSI.
ISO is a network of the national standards institutes of 154 countries on the basis of one member per country. ISO's International Standards and deliverables support, among other things, improvement of quality, safety, security, environmental and consumer protection.
IEC is the leading global organization that prepares and publishes international standards for all electrical, electronic and related technologies. One of the main IEC's objectives is to assess and improve the quality of products and services covered by its standards**.**
CEN, CENELEC and ETSI are three standardization bodies recognized as competent in the area of voluntary technical standardization. Together they prepare European Standards and make up the "European Standardization system". The European Standards (EN's) must be
Transposed into national standards and conflicting standards should be withdrawn**.** (IAEA-TECDOC-1599, 2008**)**

2.1.6 Quality assurance and quality control in Medicine:

It is now widely recognized that the attainment of high standards
of efficiency and reliability in the practice of nuclear medicine, as in other specialties based on advanced technology, requires an appropriate quality assurance program.
The concept of quality in the term "quality assurance" expresses the closeness with which the outcome of a given procedure approaches some

ideal, free from all errors and artifacts. Quality assurance embraces all efforts made to this end. The term "quality control" is used in reference to the specific measures taken to ensure that one particular aspect of the procedure is satisfactory. A clear distinction between these terms should be made.

Hence, quality assurance in nuclear medicine should cover all aspects of clinical practice.

Specifically, quality control is necessary in the submission of requests for procedures; the preparation and dispensing of radiopharmaceuticals; the protection of patients, staff and the general public against radiation hazards and accidents caused by faulty equipment; the scheduling of patients; the setting-up, use and maintenance of electronic instruments; the methodology of the actual procedures; the analysis and interpretation of data; the reporting of results and, finally, the keeping of records. (IAEA-TECDO-602, 1991)

2.1.7 Principle of quality control of instruments:

A fundamental principle in the quality control of nuclear medicine instruments is that it should be undertaken as an integral part of the work of the nuclear medicine unit and by members of the unit staff themselves. However, some aspects must be treated in collaboration with maintenance staff.

The quality control of each instrument should have as its starting-point the selection and acquisition of the instrument itself, since instruments may differ widely in their performance. The choice of an appropriate site for installation of the instrument should likewise be considered within the scope of quality control, in as far as it may influence performance.

Once received and installed, an instrument should be submitted to a series of acceptance tests designed to establish whether its initial performance conforms to the manufacturer's specifications. At the same time, reference tests should be carried out to provide data against which its subsequent performance can be assessed by routine testing weekly, monthly, quarterly, yearly etc. Finally operational checks, carried out each day the instrument is used, should be put in force. Careful records of the results of all these tests should be kept and, if these reveal unsatisfactory performance, appropriate corrective action should follow.

Such quality control does not, of course, obviate the need for the usual Preventive maintenance procedures, which should still be carried out on a Regular basis.

The success of such a scheme depends above all on its understanding and acceptance by all concerned. It further requires a clear definition of responsibilities, strict adherence to test schedules and protocols, and

proper facilities for the follow-up of test results. (IAEA-TECDO-602, 1991)

2.1.8 Implementation of quality control:

The quality control program must contain recommended schedules and Protocols for acceptance and routine testing of different classes of instruments, namely radionuclide "dose" calibrators (activity meters), Counting systems for gamma-radiation measurements in vitro, counting system for gamma-radiation measurements in vivo, rectilinear scanners and scintillation cameras.
It is emphasized that the test schedules and test protocols presented are intended for guidance only. As previously indicated, the choice of tests and the frequencies with which they are carried out have to take account of the situation in the individual nuclear medicine unit and the status of its instruments. Furthermore, it is not possible to draw up detailed test protocols applicable to all instruments in a particular class. Nuclear medicine units should, therefore, modify the given protocols to suit their own individual instruments and test devices. What is indispensable is that once appropriate individualized schedules and protocols have been agreed upon, they should be strictly followed.

2.1.9 Dose Calibrator Quality Control:

The quality control of dose calibrator , type of the test ,frequency tests are given in the following table. **(**Springer Science & Business Media, 15 Jun 2011 - Medical – page 244)

Table 2.2 Dose Calibrator Quality Control tests

Type of test	**Rate of recurrence**	**Reason of the test**
Constancy	Daily before use	To check the reproducibility of dose calibrator by the source of the known activity from day to day
Linearity	Quarterly	To check the ability of dose calibrator to measure the wide range of activity from millicurie (mCi) to microcurie (μCi) amounts
Accuracy	Annually	To check the ability of dose calibrator to measure the different levels of gamma energy (100_500 kev)
Geometry	At installation	Test for the measurement of activity as the volume of radioactive source changes

These tests should be performed after repair or preventative maintenance.

Are recommended by the camera manufacturer testing frequencies.

Years ago, the NRC in 10CFR35 required timely quality control tests performed for calibration of the dose calibrator to validate its accurate operation and established criteria for these tests. However, current 10CFR35 requires only the dose calibrator to be calibrated according to the manufacturer' s recommendations or nationally recognized standards. The following tests are essential for calibration of the dose calibrator.

- Constancy (daily)
- Accuracy (at installation, annually, and after repairs)
- Linearity (at installation, quarterly, and after repairs)
- Geometry (at installation and after repairs).

2.1.9.1 Constancy:

The constancy test indicates the reproducibility of measurements by a dose calibrator, and is performed by measuring the activity of a sealed source of along-lived radionuclide (^{226}Ra, ^{137}Cs, or^{57}Co) on frequently used settings in the dose calibrator. A deviation of the reading by more than ±10%. of the calculated activity may indicate the malfunction of the dose calibrator and hence repair or replacement. The constancy test must be done daily and at Other times, whenever the dose calibrator is used, using at least a 10 mCi (370 kBq) or more^{226}Ra or a 50 mCi (1.85 MBq) or more^{137}Cs or ^{57}Co source.

2.1.9.2 Accuracy:

The accuracy of a dose calibrator is determined by measuring the activities of at least two long-lived reference sources at their respective isotope settings, and comparing the measured activity with the stated activity. The measured activity must agree with the stated activity within±10%. Otherwise, the dose calibrator needs repair or replacement.

The activity of the reference sources must be accurate within ± 5% and one of them must have energy between 100 and 500 keV. These sources are available from the National Institute of Standards and Technology and other manufacturers whose standards are of equal accuracy. The typical reference sourcesare^{57}Co, ^{133}Ba and ^{137}Cs.

2.1.9.3 Linearity:

The linearity test indicates the dose calibrator's ability to measure the activity accurately over a wide range of values. Normally, dose calibrators exhibit a linear response for activities up to 200 mCi (7.4 GBq) to 2 Ci (74 GBq), depending on the chamber geometry and the electronics of the dose calibrator, and tend to underestimate at higher activities. The linearity test must be carried out over the range of activities from the highest dosage administered to the patient down to 30 mCi (1.11 MBq). Two common methods for checking the linearity of the dose calibrator are described below:

- **Decay Method**

In this method of linearity check, a source of ^{99m}Tc is usually used, the activity of which is at least equal to the highest dosage normally administered to the patients in a given institution. The source is then assayed in the dose calibrator at 0 h and then every 6 h during the working hours every day until the activity decays down to 30 mCi (1.11 MBq). The measured activities are plotted against time intervals on semi log paper and the "best fit" straight line is drawn through the data points (Fig. 2.3). The deviation of the point farthest from the line is calculated. If this deviation is more than ±10%, the dose calibrator needs to be replaced or adjusted, or correction factors must be applied to activities when measured in nonlinear regions.

- **Shielding Method**

This method is less time consuming and easy to perform.
A commercial calibration kit used in this method contains seven concentric cylindrical tubes or "sleeves." The innermost tube is not lead-lined and therefore provides no attenuation of gamma radiations. The other six tubes are lead-lined with increasing thickness to simulate the various periods of decay. When these tubes are placed over the source of a radionuclide (normally ^{99}mTc) in the dose calibrator, seven activity measurements represent activities at different times. From the first time measurements, calibration factors are established for each tube by dividing the innermost tube Reading by each outer tube reading. For subsequent linearity tests, identical measurements are made by the kit using a source of the same radionuclide.

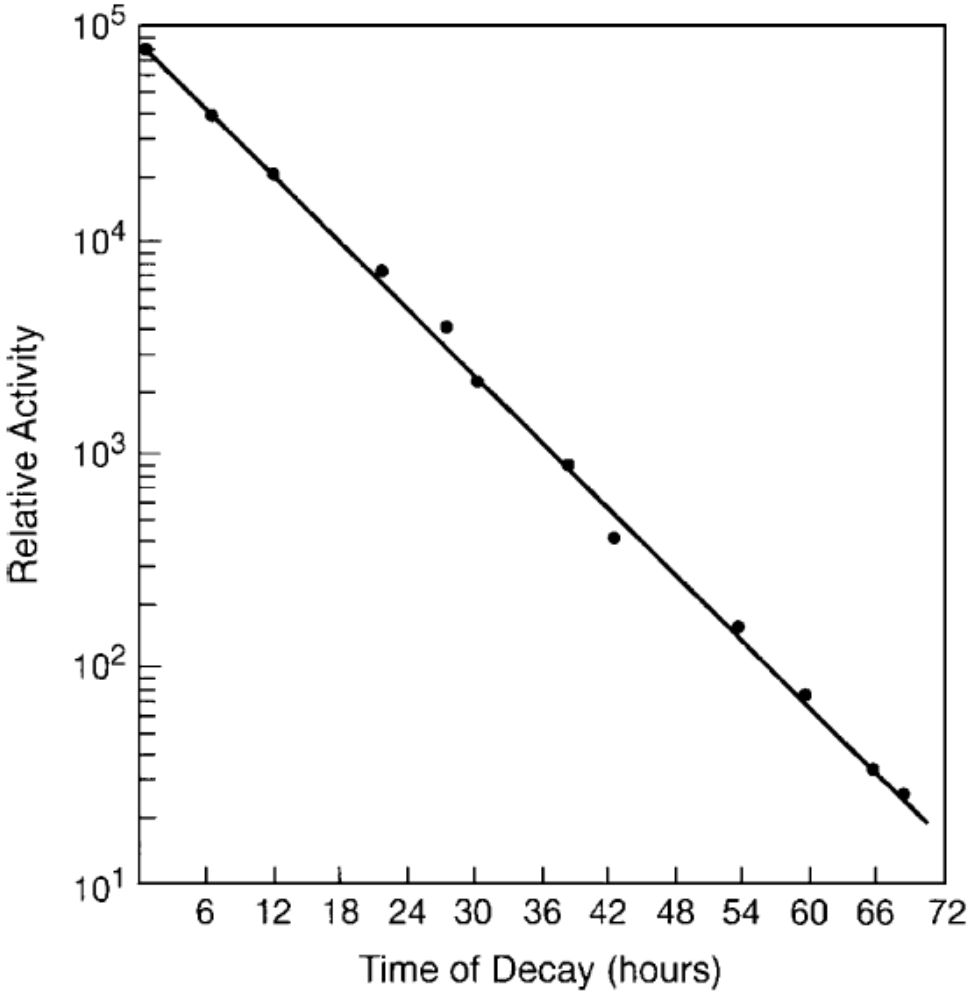

Figure 2.3 Plot of ^{99m}Tc activity versus time for the linearity check of the dose calibrator.

Each tube measurement is then corrected by the corresponding calibration factor to give identical values for all tubes. The average of these values is calculated. If each individual tube measurement falls within $\pm$10% of the average value, the dose calibrator is considered to be functioning linearly; otherwise it needs to be replaced or adjusted or to apply correction factors.

It should be pointed out that before the linearity test by the shielding method can be instituted, the dose calibrator linearity must be established first by the decay method.

2.1.9.4 Geometry:

Variations in sample volumes or geometric configurations of the container can affect the accuracy of measurements in a dose calibrator because of the attenuation of radiations, particularly the weak gamma radiations such as those of ^{125}I and ^{201}Tl. Thus, the same activity in different volumes [1 mCi (37 MBq) in 1 ml or 1 mCi (37 MBq) in 30 ml], in different containers (3-ccsyringe or 10-cc syringe or 10-ml vial) or in containers of different materials (glass or plastic) may give different readings in the dose calibrators. Correction factors must be established for changes in volume or container configuration while measuring the activity of the radionuclide in question and must be applied to similar measurements, if the difference exceeds $\pm$10%. (Gopal B. Saha, Fundamentals of Nuclear Pharmacy, Sixth Edition, New York, 2010).

2.2 Previous studies:

Many considerable studies were carried out in the scope of survey and assessment of the dose calibrator's performance through quality control tests.

A study of investigation on the performance of dose calibrators in nuclear medicine centers in Iran was done by H. Zamani Zeinali to investigate the status of the nuclear medicine (NM) centers in Iran of the performance of dose calibrators, 18 out of 54 centers providing NM services in Iran were randomly selected and Inspected in 1997.

In the first phase of the study the selected centers were inspected for performing of quality control (QC) tests of dose calibrators. The linearity of the activity response, precision, accuracy, and the physical functions of the instruments, were studied, in the second phase of the study, carried out in 2006, 28 out of 75 NM centers were investigated for QC tests performance.

The QC tests were performed by using standardized radio nuclides of Tc^{99m} and ^{137} Cs in the first phase ,and ^{99m}Tc and ^{131} I in the second phase of the studies. Standard procedures were used for carrying out the test.

According to the obtained results in the first phase of the study, 10 centers were found to be in unacceptable situation. Following this study, all the concerned NM centers were informed about the results, and at the same time the repair and adjustment of the dose calibrators were requested. In addition, the appropriate training courses along with the QC testing manuals were provided to the centers. Based on the data of the second phase of the study, only 6 NM centers were in unacceptable situation. The results indicated the effectiveness of the improvements carried out in the working procedures of the centers during interval between the two phases of investigation. (International Journal of Radiation Research, 2008, Volume 6(64-69)).

Then By Zhenya Krasteva ,The purpose of this study is Surveillance on performance of dose calibrators in nuclear medicine (NM) centers in Bulgaria.

The methods used for QC are based on established international and national recommendations. For each type of dose calibrator requirements of the producer are taken into account. Depending on the type of dose calibrator there might be a need to modify QC procedures. The following sources of photon radiation were used for The measurements ^{99m}Tc ,^{137} Cs and ^{133}Ba. To ensure The proper

operation of a dose calibrator , four QC parameters must be tested: accuracy, precision, constancy and linearity.
The results from the measurements showed that the parameters that were traced for the dose calibrators are within the Bulgarian and International standards. It is essential to perform daily testing for background activity and constancy. Deviations from normal values of these two parameters is the first sign of degradation of the dose calibrator. Regular QC should cover precision, accuracy and linearity of the instrument . According to IAEA standards and Ordinance NO 30 (31October 2005) of Ministry of Health. That will guarantee accuracy of the used patients radioactive doses and therefore proper practice of nuclear medicine diagnosis.

ELTAHIR, 2011, Assessment of Radiation Dose Calibrators Performance in Nuclear Medicine Departments in Some hospitals**.** This study was carried out to assess the performance of dose calibrators that working in some nuclear medicine departments in Sudan. Three departments were included in the study, Radiation and isotopes center of Khartoum (RICK), Elnilein medical diagnostic center, and Shendi center of nuclear medicine and oncology, University of Shendi. Four quality control tests were carried out using two standard radionuclides, ^{137}Cs and ^{57}Co. Tests include accuracy, constancy, linearity, and geometry. All results that obtained from the study has been compared with the international standard (±10%) and the results showed that all dose calibrators has good performance and there is no need for any correction tables or factors or maintenance.

Abdallah, 2014, Assessment of ^{99m}Tc dose calibrator performance in Nuclear Medicine Department, Nuclear medicine uses many different radioactive isotopes for radiation diagnostics and for therapy. The amount of radioactivity has to be determined exactly before it is applied to a patient. The Dose calibrators have to measure the radioactivity of gamma and beta with different energies precisely for high quality imaging and for applying the right amount of radiation to treat disease. This study was carried out to assess the performance of dose calibrators which work in nuclear medicine departments in Khartoum state. Two departments were included in this study, Radiation and isotopes center of Khartoum (RICK) and Elnileen medical diagnostic center. Four quality control tests were carried out using two standard Radio nuclides, ^{137}Cs and ^{57}Co, which were accuracy, constancy, linearity and geometry. All results that obtained from the study has been compared with the international

standard (±5%) and the results showed that all dose calibrators has good performance and there is no need for any correction tables or factors or maintenance.

Mosaab, 2015, Assessment of ^{99m}Tc ^{99}Mo Dose Calibrator Performance For Nuclear Medicine Department in Al Nelein Diagnostic Center, Nuclear medicine uses many different radioactive isotopes for radiation diagnostics studies and for therapy. The amount of radioactivity has to be determined exactly before it is applied to a patient. The dose calibrator has to measure the radioactivity of gamma and beta with different energies precisely for high quality imaging and for applying the right amount of radiation to treat diseases. This study was carried out to assess the performance of dose calibrator which is used in nuclear medicine department in Elnielin Medical Diagnostic Center (Khartoum state). The study period was form July 2014 to February 2015. Four quality control tests were carried out using standard radionuclide, ^{137}Cs. The tests included accuracy, constancy, linearity and geometry. All results that were obtained from the study were compared with the international standard (±5%) and the results showed that the dose calibrator under the study is of good performance and there is no need for any correction tables or factors or maintenance for the time being.

Osama and et al, 2016, Evaluation of dose Performance calibrator in Radiation Therapy and Nuclear Medicine in Center Khartoum (Nuclear Medicine Department),This study is concerned with quality control of the dose calibrator which is located in the Radiation Therapy and Nuclear Medicine Center of Khartoum. The objective of the study is to evaluate the dose calibrator performance. Quality control tests were performed in the period between Dec/ 2015 and Jan/2016. They included general observations to the components of the device, background measurements, precision, accuracy, continuity, linearity and geometric dependency. Two standard radionuclide's ^{137}Cs and ^{99m}Tc were utilized for the purpose of the study and has come to the following results, all the components of the device work properly and readings for background radioactivity were in the acceptable range (0.562+0.45). Concerning Precision testing the error of the reading was (0.39%), and it was within the accepted range. Concerning accuracy testing the error of the readings

was within (0.27%), and it was within the accepted range. For constancy test the error value of readings was (2.47%), and it was also within the accepted range and the error of readings concerning linearity testing was (3.7%), and it was within the accepted range and finally the results of geometric dependency showed that the correction factor was within the accepted range (0.95-1.05). All the results showed that the devise has good performance and there is no need for any correction and maintenance.

Mawada, 2016, Assessment of Radiation Dose Calibrator Performance in the Nuclear Medicine Department of the National Cancer Institute –Wad Madani, Nuclear medicine uses many different radioactive isotopes for radiation diagnostic studies and for therapy . The amounts of radioactivity has to be determined exactly before it is applied to patients. The dose calibrator has to measure the radioactivity of gamma and beta with different energies precisely for high quality imaging and for applying the right amount of radiation to have good images which give good diagnosis and effective treatment of diseases. This study was carried out to assess the performance of dose calibrator which is used in nuclear medicine in the National Cancer Institute –wad Madani (Gazera state) . The study period was from October 2015 to February 2016. Four quality control tests were carried out using standardradionuclide,^{137}Cs. The tests included accuracy, constancy, linearity and Geometry. All results that were obtained from the study were compared with the international standard (±5%) and the results showed that the dose calibrator under the study was of good performance and there is no need for any correction tables or factors or maintenance for the time being. This study was carried out to assess the performance of dose calibrator which is used in nuclear medicine in the National Cancer Institute –wad Madani (Gazera state). The study period was from October 2015 to February 2016. Four quality control tests were carried out using standard radionuclide, ^{137}Cs . The tests included accuracy, constancy, linearity and Geometry. All results that were obtained from the study were compared with the international standard (±5%) and the results showed that the dose calibrator under the study was of good performance and there is no need for any correction tables or factors or maintenance for the time being.

Almubarak, June 2016, Assessment of Dose Calibrators Performance in Nuclear Medicine Department in Sudan, This study managed to evaluate the performance of the dose calibrators which work in nuclear medicine departments in Sudanese centers by using four quality control tests accuracy, constancy, linearity and geometry. These four tests was performed for two dose calibrators, Capintec PTW CURIEMENTOR4 (RICK center), and Capintec CRC25R (Elnilein center) the results of the quality control tests revealed that the parameters that were traced for dose calibrators are within the limits of the International standards (±5%). It is essential to perform daily tests for background activity, constancy, and accuracy. A deviation from normal values of these parameters is the first sign of degradation of the dose calibrator. Regular QC should cover precision, accuracy, linearity, and geometry of instrument, according to IAEA standards, e.g. (IAEA TECDOC-602 and 1599), that will guarantee accuracy of the used patient's radioactive doses and therefore proper practice of nuclear medicine diagnosis. According to descriptive analytical method, it is found that the NM centers generally have acceptable situation in terms of the QC measures for dose calibrator.

This is an experimental study deals with evaluation of QC program of dose calibrator. The importance of this study is to highlight the importance of the QA program in NM department, increase diagnosis accuracy and reduce the dose for both patient and technologist. All this cannot be achieved without QC.

For radionuclide dose calibrators, the researcher managed to evaluate the performance of the dose calibrators which work in nuclear medicine departments in Sudanese centers by using four quality control tests accuracy, constancy, linearity and geometry. These four tests was performed for two dose calibrators, Capintec PTW CURIEMENTOR4 (RICK center), and Capintec CRC-25R (Elnilein center) The results of the quality control tests revealed that the parameters that were traced for dose calibrators are within the limits of the International standards (±5%). It is essential to perform daily tests for background activity, constancy, and accuracy. A deviation from normal values of these parameters is the first sign of degradation of the dose calibrator. Regular QC should cover precision, accuracy, linearity, and geometry of instrument, according to IAEA standards, e.g. (IAEA TECDOC-602 and 1599), that will guarantee

accuracy of the used patient's radioactive doses and therefore proper practice of nuclear medicine diagnosis.

According to descriptive analytical method, it is found that the NM centers generally have acceptable situation in terms of the QC measures for dose calibrator.

CAPTER THREE

MATERIALS AND METHODS

3.1 Materials:

3.1.1 Dose Calibrator:

The nuclear medicine department of the Royal care International Hospital uses dose calibrator, Biodex model Atom lab 400 dose calibrator 086-335, Serial No 10040102, manufactured on April 2010 made in USA.
(See Appendix A)

3.1.2 Standard radionuclide source:

The standard radionuclide source used in this study to perform quality control tests was ^{99m}Tc.
The specifications of standard radionuclide source were the short half-life of 6.02 hours and Energy (Eγ**)** of 140.51 kev, ^{99m}Tc was prepared as solution in 10 ml sample glass vial whose activities from 2.60 mCi to 190 mCi.
(See Appendix B)

3.1.3 Sample glass vial:

The volume of glass vial used for testing is 10 ml.
(See Appendix C)

3.1.4 Plastic syringe:

The syringe of (5 cc) was used in the test of geometry.
(See Appendix D)

3.2 Methods of data collection &analysis:

The tests included Precision, Linearity and geometrical dependency on the Dose calibrator using ^{99m}Tc, the tests of accuracy and constancy are excluded from the study because there was no long -lived source in the center.
The dose calibrator was tested in place without any movement, and with some modifications to the quality control procedures according to the dose calibrator type and manufacturers recommendations. The data were collected through observations and, testing.
That data were analyzed using Microsoft office 2007- Excel program under windows-Xp.

3.2.1 Physical inspection:

- Dose calibrator was inspected the instrument housing for evidence of damage. Particularly it was examined the surroundings of the ionization chamber for signs of deformation or indentation.
- It was inspected all controls plug-in modules push buttons and switches.
- It was inspected all controls, check that none were missing and examine cables, plugs and socket for evidence of damage.
- All accessories were inspected such as remote handing devices source holders; check that none are missing or damage.
- She checked any accompanying sealed radiation sources for external radioactive contamination or leakage. Both operation and service manuals checked that are available.
- The compatibility of the power supply requirements checked with available supply and makes any necessary adjustments.

3.2.2 Background Test:

Contamination in the chamber or drift in the electronics can result in a non-zero reading (positive or negative reading). If this is not checked and corrected, then measurements taken will be systematically either too high or too low. Contamination in the chamber or sample holder should be

eliminated as much as possible and zero offsets and general background should be set to zero with the controls provided on most dose calibrators.

Frequency:

Daily

Procedure

A reading was taken without a source in the dose calibrator.

3.2.3 Precision Test:

Precision checks the short term reproducibility of the dose calibrator .it is measured by taken 10 separate readings of a reference source (^{99m}Tc in a vial), with the source removed from the chamber between readings. All 10 readings should be within ±5% of the mean of the readings.

Frequency:

Precision testing frequency is usually performed quarterly.

Procedure:

- Approximately (91 mCi) of ^{99m}Tc put in a vial.
- The source was inserting into the source holder by means of the remote handling device and introduces the source holder into the dose calibrator.
- Sufficient time was allowed for the reading to stabilize.
- The activity was measured and recorded, background reading subtracted to obtain the net activity in millicuries.
- 10 separate readings were taken of the source and record them.
- The source holder was removed from the dose calibrator and extracts the source by means of the remote handling device.
- To assess precision, calculate mean of the 10 readings (Mean Activity).
- The percent difference calculate from mean for each of the 10 individual readings as follows:

$$\frac{\text{Individual Reading - Mean Activity}}{\text{Mean Activity}} * 100\ \%$$

- Results of calculations were recorded.
- The percent of difference for all 10 readings should all be less than ±5% for proper operation of the dose calibrator

3.2.4 Linearity test:

Linearity testing assesses the ability of the dose calibrator to indicate the correct activity over the range of use of the calibrator. This test is performed by the use of radioisotope ^{99m}Tc with the short half-life of 6.02 hours. This test was carried out using an amount of 7.030 MBq (190mCi) ^{99m} Tc as solution in avail and measuring the activity by a dose calibrator for a relatively long period of time up to 45 hours. If the measured error of the activities of the source by the dose calibrator exceeded ±10%, the instrument was considered not to function properly.
The NRC requires that linearity be tested upon installation and at least quarterly thereafter as well as after repair.

Frequency:

The test is performed at installation and at least every three months thereafter.

Procedure:

Using the decay method

- The ^{99m}Tc vial was assay in the dose calibrator, background subtracted to obtain the net activity in millicuries. The date and time Recorded to the nearest minute, and net activity on a dose Calibrator. This first assay was done in the morning at 9 am.
- The assay was repeated after 7 hours, 14 hours, 21 hours, 28 hours, 35 hours, and 45 hours.
- The measured activities are then plotted versus time on a semi-logarithmic graph. Label the vertical axis in millicuries to represent the measured activity and label the horizontal axis in hours elapsed.
- A best-fit straight line was drawn by the researcher through the data points; the best-fit straight line drawn through the data points is plotted (either by eye or by using a least-squares curve fitting algorithm).

For each data point, the difference between the measured activity and the activity on the best-fit straight line at that point should be less than ±5%. Calculate its deviation from the value on the line using the following equation:

$$\text{Deviation} = \frac{A_{\text{observed}} - A_{\text{line}}}{A_{\text{line}}}$$

If the worst deviation is more than plus or minus 10%, the dose calibrator should be repaired or adjusted, if this cannot be done, it will be necessary to make a correction table or graph that will allow converting from activity indicated by the dose calibrator to true value.

3.2.5 Geometry Test:

Geometric dependency means that the indicated activity does not change with volume or configuration of the source. This test must be done according to protocols accepted by the appropriate state regulatory agencies or the Nuclear Regulatory Commission (NRC). Geometry dependence testing is commonly performed at installation; after repair or moving the instrument.
This test should be performed using a syringe that is normally used for injections.

Frequency:

Upon installation, after service or dose calibrator movement**.**

Procedure:

The activity is then diluted with water to 2 ml, 3 ml, 5 ml,

- A small sample (1ml) of ^{99m}Tc was placed in 5cc syringe (activity 2.60 mCi).
- Measured the activity of the sample in the dose calibrator and the reading was recorded.
- The syringe was removed from the calibrator.
- The activity is then diluted with water to 2 ml, and the measurement was repeated, then the reading was recorded.
- "Step 4" was repeated until final volume is 4 ml.
- Background is subtracted from each reading to give net activity.

- One of the volumes is then selected as standard, the measurement for the 1 ml. Divide the 1 ml mCi by the mCi recorded for all the other volumes, The correction factor for each volume is then calculated as follows:

$$\text{Correction factor} = \frac{\text{Standard Volume Activity Reading}}{\text{Activity Reading for other Volume}}$$

- All of the volumes should be within ±5%. If greater than 5% then the health physicist must be notified and unit serviced.

CHAPTER FOUR

RESULTS

4.1 Precision test:

Table 4.1 Shows precision test of radionuclide calibrator

Background Reading = 0.1 mCi

No	Reading in mCi Net
1	90.7
2	90.7
3	90.7
4	90.7
5	90.4
6	90.4
7	90.3
8	90.0
9	90.0
10	90.15
Mean	90.4
SD	0.294

4.2 Linearity test:

Table 4.2 Shows Linearity test of radionuclide calibrator, using Tc^{99m}

No	Time(hr)	Activity(mCi)
1	0	190
2	7	84.4
3	14	37.6
4	21	13.28
5	28	5.98
6	35	2.65
7	45	0.829

The readings were then plotted on semi-log graph paper together with a line which indicates the decay of the radionuclide as shown in figure below:

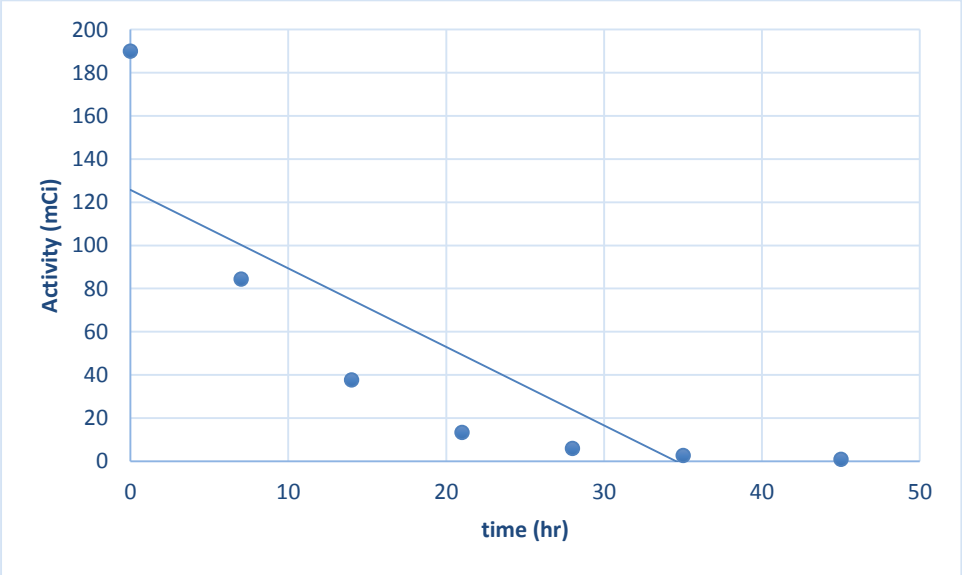

Figure 4.1 Plot of linearity check of the dose calibrator in RCIH.

4.3 Geometry Test:

Table 4.3 shows the effect of calibrator Geometry on the activity according to volume.

Background Reading = 0.1 mCi

No	Volume(ml)	Net Reading in(mCi)
1	1 ml	2.60
2	2 ml	2.60
3	3 ml	2.60
4	4 ml	2.59
Mean		2.59
SD		0.005

CHAPTER FIVE

DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Discussion:

Precision checks the short term reproducibility of the dose calibrator. It was measured by taking 10 separate readings of a reference source (^{99m}Tc in a vial). The mean of readings was (90.4) and the standard deviation was (0.294), the precision should be such that all individual measured activities on the source are within ± 5% of the mean measured activity.
These results confirm acceptable performance and showed high precision in dose calibrator.

Table (4.2) Showed Linearity test of radionuclide calibrator, the survey was done over two days to investigate the dose calibrator ability to indicate the correct activity over its range of use for relatively high activities and low activities. The linearity of the activity response should be such that all individual activities measured in the test are within ±10% of the values corresponding to the straight line fitted to the data points.
The results show that the dose calibrator readout is linear for the activity through 45 hours, and the percentage errors between calculated and measured readings are within international standards (± 5%) and the dose calibrator passed the test.

Table (4.3) showed geometry test to show if there is any change in the activity reading according to the increase of the activity volume.

The test showed the activity measured by syringes volumes (1ml, 2ml and 3ml) gave same readings in activity (2.60 mCi), and the activity reading of the syringe with volume 4ml was (2.59 mCi). The standard deviation was (0.005). These results shown that the activity result was within the accepted range ± 5%.

When comparing the results of this study with the results of previous studies it was found that they agreed with it.
All quality control tests in previous studies included the accuracy test, but this study did not perform the accuracy test due to unavailability of long-lived radionuclide in the center under the study.

5.2 Conclusion

It was good to find a solution when a problem arises, but it is better
To foresee the problem so that it can be avoided.
For radionuclide dose calibrator, the researcher managed to evaluate the performance of the Dose Calibrator working in Royal care International Hospital (Khartoum State). This was done by different methods.
The tests of reproducibility of the dose calibrator and linearity and Geometric dependency testing were performed for Biodex model Atom lab 400 dose calibrator 086-335, Serial No 10040102.
The results of the quality control tests revealed that the parameters that were traced for dose calibrator are within International standard (± 5%).
Regular QC should cover Precision, linearity and geometry of instruments according to IAEA standards.
The tests were done using one radionuclide (^{99m}Tc), because it was the only available radionuclide at the department under study. So this research did not include a test of accuracy because this work needs more than one long-lived radionuclide.
We concluded that from the results of the study shown that Royal Care International Hospital has an acceptable situation in terms of the quality control measurement for the dose calibrator, and it was working properly.

5.3 Recommendations:

- Preparation and formulation quality control system applicable in nuclear medicine practice in Sudan for all nuclear medicine equipments.
- Providing the relevant documentation to the nuclear medicine centers to implement a comprehensive QC program properly.
- Encouraging the cooperation of the relevant regulatory bodies and nuclear medicine centers in Sudan.
- Encouraging the cooperation of the relevant regulatory bodies in Sudan with international atomic energy agency to provide technical support, training courses and quality control tools for nuclear medicine centers through regional and national projects.
- Q C programs in the N.M department should be performed at daily, weekly and annually.
- Training programs to the N.M staff on Q.C should be set up and implemented in any N.M department in Sudan.

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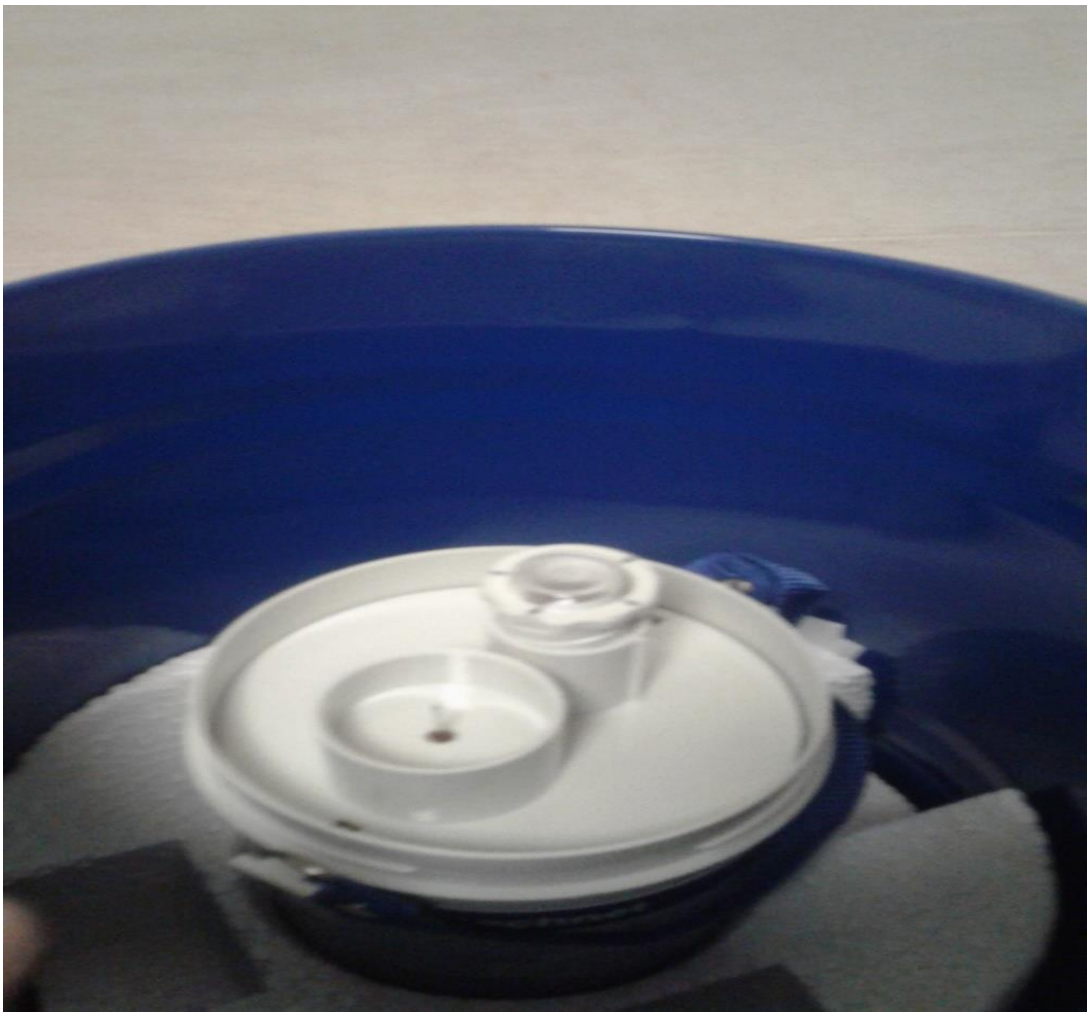
Appendices

Appendix (A) shows the dose calibrator Biodex model Atom lab 400.



Appendix (B) shows generator of Standard Radionuclide (source of Tc^{99m}).

Appendix (C) shows the volume of glass vial used for testing (10 ml).

Appendix (D) Shows the syringe of (5 cc) was used in the test of geometric dependency.

Appendix (E) shows the remote handing devices for source holder.